

3D Imaging & Simulations Corp.

510(k) Summary for K131442

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date Prepared: September 3, 2013

1. Company and Correspondent making the submission:

Name – 3D Imaging & Simulations Corp.
Address – 815, Tamnip-Dong, Yuseong-Gu, Daejeon, Korea
Telephone – +82-42-931-2100
Fax – +82-42-931-2299
Contact – Jiin Jung / COO
E-mail – jijj@3DISCimaging.com

SEP 06 2013

2. Device :

Trade/proprietary name : FireCR Dental
Common Name : Computed Radiography Scanner System
Classification Name : Extraoral source x-ray system

3. Predicate Devices :

Manufacturer : Soredex
Device : DIGORA Optime
510(k) Number : K041050 (Decision Date - Apr. 19. 2004)

4. Classification Name & Citations :

Extraoral source x-ray system., 21 CFR 872.1800, Pro Code MUH.

5. Description :

5.1 General

The FireCR Dental is Computed Radiography Reader which produces the X-ray diagnostic image in digital format instead of using traditional screens and film. This device utilizes reusable X-ray storage phosphor plate (Imaging Plate) that is sensitive to X-ray and stores latent image when it is exposed to X-ray. After X-ray exposure to the X-ray storage phosphor plate, X-ray storage phosphor plate is scanned by means of laser in the device. Latent image in the X-ray storage phosphor plate is released in a form of light by laser scanning. Then the light is collected and converted into a form of digital image. The signal processing is made to

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the digital image data such as the digital filtering, the gain & offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, then stored locally, sent to an archive, printed or sent to PACS system.

After acquisition of latent image from the X-ray storage phosphor plate, it is erased thoroughly to be reused.

5.2 Main Feature

Experience the Benefits of Digital Imaging

The full-featured **Fire CR Dental Reader** from **3D Imaging & Simulations Corp.** rapidly and affordably delivers high-quality digital images for busy dental practices.

Compact & Affordable

The **FireCR Dental Reader** is compact and affordable, helping to increase patient throughput and improve the overall productivity of your practice. With its small footprint, the reader fits seamlessly into even the most space-challenged dental offices and exam rooms.

Elegant Design & Streamlined Operation

The **FireCR Dental Reader's** elegant design belies a powerful yet easy-to-use system that gets the job done day in and day out.

The reader is DICOM 3.0 compatible with existing systems and uses a full range of low-cost, reusable bitewing and intraoral imaging plates that are easier and faster to position than intraoral digital sensors.

5.3 Product features

- Photomultiplier Tube (PMT)
- IP size : 0, 1, 2, 3 and 4c
- Wide dynamic range with 16-bit digitization
- DICOM3.0 standard compliance
- User Selectable Scanning Resolution : 35um and 64um

6. Indication for use :

The FireCR Dental imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media

7. Comparison with predicate device :

3D Imaging & Simulations Corp. believes that the Dental Computed Radiography Reader

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(FireCR Dental) is substantially equivalent to DIGORA Optime of Soredex.

		FireCR Dental 3D Imaging & Simulations Corp.	DIGORA Optime Soredex
510(k) number		-	K041050
Intended Use		This device is a Dental Computed Radiography System and intended for use in producing digital X-Ray images for dental radiography (intra oral) purposes.	The Digora Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.
Physical Char.	Overall Dimensions	Reader 185 x 100 x 293mm	Reader 190 x 200 x 383mm
	Imaging Area	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm Size 4c : 48 x 54mm	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm Size 4c : 48 x 54mm
	Effective Pixel Pitch	35um, 64um	35um, 64um
	Spatial Resolution	14.3 lp/mm @ 35um 7.8 lp/mm @ 64 um	14.3 lp/mm @ 35um 7.8 lp/mm @ 64 um
	Image Matrix	Size 0 343 x 484 @ 64um 628 x 885 @ 35um Size 1 375 x 625 @ 64um 685 x 1143 @ 35um Size 2 484 x 640 @ 64um 886 x 1171 @ 35um Size 3 421 x 843 @ 64um 771 x 1542 @ 35um Size 4c 750 x 843 @ 64um 1370 x 843 @ 35um	Size 0 343 x 484 @ 64um 628 x 885 @ 35um Size 1 375 x 625 @ 64um 685 x 1143 @ 35um Size 2 484 x 640 @ 64um 886 x 1171 @ 35um Size 3 421 x 843 @ 64um 771 x 1542 @ 35um Size 4c 750 x 843 @ 64um 1370 x 843 @ 35um
	Weight	4.7kg	9.8kg
	Imaging Device	High Sensitivity Photo Multiplier Tube (s-PMT)	High Sensitivity Photo Multiplier Tube (s-PMT)
	Imaging Device	High Sensitivity Photo Multiplier Tube (s-PMT)	High Sensitivity Photo Multiplier Tube (s-PMT)
Operational Char	Operating Condition	Temperature : 15-30°C Humidity: 15%-95% RH	Temperature: 10 - 40 °C Humidity: 30 - 90% RH
	Power Requirements	100 – 240V, 50/60Hz	100 – 240V, 50/60Hz
	Methods of Exposure	Register Patient -> X-ray Exposure	Register Patient → X-ray Exposure
	X-ray Absorber	Imaging plate	Imaging plate
Functional Char.	Output Data	Dicom3.0 Compatible	Dicom3.0 Compatible
	DQE @ 10% eff.	2.6 lp/mm	2.4 lp/mm
	MTF @ 3 lp/mm	34%	32%
	Defect Compensation	By Calibration	By Calibration
	Dynamic Range	16bit	14bit
	Image	Single image processing	Single image processing

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		FireCR Dental 3D Imaging & Simulations Corp.	DIGORA Optime Soredex
	Processing	parameter is used	parameter is used
	DICOM Compatibility	DICOM 3.0 Compliant	DICOM 3.0 Compliant

The FireCR Dental's imaging principle, physical characteristics, target population and intended use are the same as those of DIGORA Optime. However, the differences in the design are follows:

- The technical specification (including Spatial Resolution, Operating Condition, DQE, MTF, Dynamic range), mechanical structure and physical appearance of the FireCR Dental is little different from the DIGORA Optime. Additional information can also be found in the FireCR Dental Operation Manual provided in this submission.
- The testing of the FireCR Dental demonstrates that the performance is substantially equivalent to the predicate devices cited above.

In clinical considerations,

- The rating was considered equivalent by dentists.
 - As a result of Clinical Study, FireCR Dental is considered that Image quality is equivalent to the Predicate Device. And FireCR Dental represents an effect for diagnosis of patient.

The FireCR Dental described in this 510(k) has the same intended use and similar technical characteristics as the DIGORA Optime of Soredex. The similarities and differences between these systems are described in the table shown above.

The similarities are as follows.

*Similarity of **Intended use with DIGORA Optime***

*Similarity of **Capturing image, Image Processing, and DICOM compatible features with DIGORA Optime***

*Similarity of **X-ray exposing technique with DIGORA Optime***

*Similarity of **Effective Pixel Pitch.***

*Similarity of **Spatial resolution.***

*Similarity of **X-ray absorber material with DIGORA Optime***

*Similarity of **Image making process with DIGORA Optime***

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Similarity of **Energy Sources, Source to skin distance with DIGORA Optime**

Similarity of **workstation and operating system with DIGORA Optime**

A difference is as follows.

(1) Difference in Dynamic Range

DIGORA Optime's dynamic range is 14bit but FireCR Dental is 16bit. Therefore FireCR Dental shows more dynamic range in image than DIGORA Optime.

In summary, The FireCR Dental does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

8. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification 3D Imaging & Simulations Corp. concludes that the Computed Radiography Scanner System (FireCR Dental) is safe and effective and substantially equivalent to predicate devices as described herein.

10. 3D Imaging & Simulations Corp. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

3DISC Americas
% Daniel Kamm, P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K131442
FireCR Dental Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 29, 2013
Received: July 31, 2013

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131442

Device Name: FireCR Dental Imaging System

Indications for Use:

The FireCR Dental Imaging System is indicated for capturing, digitization and processing of intra-oral x-ray images stored in imaging plate recording media.

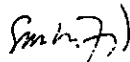
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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